Neurosurgical Forum LETTERS TO THE EDITOR

The ancient “apples and oranges” conundrum: a call for methodological precision

TO THE EDITOR: In a recently published article, Gillis et al.¹ proposed to analyze the improvement in several radiographic parameters in patients submitted to 1- and 2-level anterior cervical discectomy (ACDF) with lordotic cages through measurements performed on lateral radiographic images at 3 time points: preoperatively, at 6 weeks, and at 1 year postoperatively (Gillis CC, Kaszuba MC, Traynelis VC: Cervical radiographic parameters in 1- and 2-level anterior cervical discectomy and fusion. *J Neurosurg Spine* 25:421–429, October 2016).

In such a study, although accuracy may not be a key concern (as radiographs obtained with 10° of neck extension may be interpreted as neutral if all further measure-

ments are performed on similar radiographs with 10° of extension), precision (i.e., the consistency between different measurements) is of paramount importance in order to avoid comparisons between images that are simply not comparable.

Although the article presents an extensive description of the obtained radiographic measurements, a simple analysis of Figs. 1 and 2 generates serious questions about the methodological quality of the performed measurements, especially regarding their precision. For instance, Fig. 1A and B, which are clearly not perfect lateral radiographs (as it can be noted by the double shadow of the facet joints, *arrows* in Fig. 1B), are compared with a perfect lateral radiograph (Fig. 1C, properly overlapping facets). More concerning than that is the fact that, while Fig. 1A seems to be a neutral radiograph, Fig. 1B already demonstrates some degree of cervical extension, which becomes much more pronounced in Fig. 1C (a measured difference of 9° between Fig. 1A and 1C). This discrepancy becomes even

FIG. 1. Reprint of Fig. 1 from the article, with the *black lines* and degree measurements and the *white arrows* added to originals. The angle between C-1 and the superior endplate of C-5 was measured on the preoperative image as well as at the 1-year follow-up (note that the same lines used by the authors were used in order to avoid even minimal discrepancies in the measurements). There is a change from 28° to 37° at the angle of C1–5 between the preoperative and postoperative images, confirming that the postoperative radiograph was obtained 9° in extension in relation to the preoperative radiograph. Also note that the mandible/bite line is also not parallel to the ground in panel A, as it is in panel C. Please also note the double shadow of the facet joints in panels A and B (*white arrows*), confirming that the radiograph is not a perfect lateral as it is in panel C. Modified from Gillis et al.: *J Neurosurg Spine* 25:421–429, 2016, with permission. Figure is available in color online only.

FIG. 2. Reprint of Fig. 2 from the article, with the *black lines* and degree measurements and the *white arrow* added to originals. The angle between C-1 and the inferior endplate of C-7 was measured preoperatively as well as at the 1-year follow-up (note, again, that the same lines used by the authors were used in order to avoid even minimal discrepancies in the measurements). There is a change from 22° to 48° at the angle of C1–7 between the preoperative and postoperative images, confirming that the postoperative radiograph was obtained 26° in extension in relation to the preoperative radiograph. As a minor detail, please note the *arrow* at the 1-year follow-up demonstrating a pulled-out screw at C-5, suggesting pseudarthrosis. Modified from Gillis et al.: *J Neurosurg Spine* 25:421–429, 2016, with permission. Figure is available in color online only.

more evident in Fig. 2, which shows a neutral radiograph in Fig. 2A, while Fig. 2B, and especially Fig. 2C, are clearly lateral radiographs in extension—a measured difference of 26° between Fig. 2A (preoperatively [22°]) and Fig. 2C (1-year postoperatively [48°]).

It is important to highlight that, in patients with significant cervical kyphosis, it has already been demonstrated that neck extension by itself has a limited effect in terms of its ability to change the sagittal balance, usually being insufficient to reverse the cervical kyphosis to a physiological lordosis.² However, this is clearly not the case of the patients analyzed in the study by Gillis et al., all of whom presented with preoperative C1–7 lordosis greater than 40° according to Table 2 of the original article. In such a group of patients, classic biomechanical studies have already demonstrated that each healthy level in the subaxial cervical spine may demonstrate a range of motion of up to 10° between flexion and extension.^{3,4} The authors could possibly argue that all radiographs were obtained in a naturally neutral position, which would theoretically represent the patient's rest position. In such a scenario, the increase in the overall cervical lordosis after the ACDF could be attributed, for example, to a reduction in the cervical muscle spasms, ultimately reflecting an improvement in the cervical biomechanics. However, it is quite questionable that patients with only 1 or 2 levels affected by spondylotic changes would present with such a narrow comfort zone that would enable precise estimation of the effects of ACDF on their cervical biomechanics. Ultimately, if there is not a strict protocol to obtain standard neutral radiographs (for example, by aligning the mandible/bite line with the horizontal plane), it is very likely that the specific degree of cervical extension

in each radiograph (and, therefore, most of the values in Table 2 in the article) was ultimately determined by each patient's random choice in their self-positioning within a wide range deemed to be within such a “comfort zone,” or, more likely, by the gross estimation of the x-ray technologist who positioned the patient's head in what he or she believed to be a roughly neutral position.

This “apples and oranges” comparison effect becomes even clearer in Fig. 2. Besides from artificial changes in the degree of neck extension (as revealed by the different relationship of the mandible/bite line from Fig. 2A to 2C), how would it be possible, aside from an artificial effect secondary to neck extension, for the overall cervical lordosis to improve from 5.4° at 6 weeks to 17.4° at 1 year if the improvement in the segmental lordosis at the operated levels decreased from 10.3° at 6 weeks to 7.2° by 1 year (likely due to small subsidence of the allograft)?

If such methodological concerns affected not only the measurements performed in Figs. 1 and 2 but actually every radiographic evaluation, all values described in Table 2 regarding C2–7 lordosis, C1–7 lordosis, T-1 slope, and C2–7 sagittal vertical axis may simply be unreliable, ultimately rendering any further statistical analysis performed on such values devoid of any meaningful clinical implications.

Ultimately, the only values that can be expected to be unchanged even when using radiographs with different degrees of neck extension are those of focal lordosis and disc height. However, after a careful analysis, even these values become amenable to criticism. It is hard, for example, to explain how 6° lordotic allografts used in a 1-level ACDF would lead to only an average of 3.92° of improvement in the focal lordosis at 6 weeks (Table 2).

More surprising, however, is the increase in such focal lordosis from an average 3.92° at 6 weeks to 5.71° at 1 year. If that loss from 6° to 3.92° was real and related to cage subsidence, for example, any further increase in the focal lordosis of a rigidly plated level at 1 year becomes quite hard to explain. Even with dynamic plates, only parallel movements (and not angular ones that may lead to an increase in the focal lordosis) can occur. Such parallel movements would only occur in the case of cage subsidence and would only affect the disc height but not the segmental lordosis.

It is not a strict requirement that every radiographic study in spine surgery involve prospectively collected data as well as measurements performed by a board-certified radiologist. However, if such plain discrepancies become so clearly evident even in the only 2 figures that were chosen to illustrate the study (supposedly because they were believed to be the best representative images), one may only question the actual reliability of the measurements performed on the other unpublished radiographs.

We sincerely hope that the authors may be able to provide a robust defense against such arguments, ultimately rescuing the scientific merit of their paper. Otherwise, rather than confirming the initial thesis the authors intended to prove, this article will remain in the scientific literature as a didactic case study of how the results of a carefully designed study, with a sizable patient cohort and a proper statistical analysis of the obtained results, can be simply invalidated in its totality because of the lack of precision in the performed measurements.

Unfortunately, taking into account the deep concerns regarding the precision of the radiographic measurements of the study by Gillis et al., we are afraid that it is not simply the case that the conclusions based on the obtained data may not be right. As Wolfgang Pauli, the Nobel Prize-winning Austrian-Swiss physicist, is said to have once stated (in German), "That is not only not right; it is not even wrong."

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Disclosures

The authors report no conflict of interest.

Response

We appreciate the interest Drs. Mattei and Teles have expressed concerning our recent publication and are pleased to provide clarification of the work. The first concern focuses on the radiographic images. This is a retrospective study, and thus the radiographs were obtained using the protocol of the Department of Radiology at Rush University Medical Center. Neutral radiographs are obtained with the patient in the upright erect position with the knees fully extended. The patient is asked to stand in a comfortable position looking forward, i.e., standard radiological technique. This method was consistently used with each patient, providing the "accuracy," which is critically important. Specific protocols, such as aligning the mandible or bite line to the horizontal plane, are artificial and therefore would not provide any meaningful, clinically relevant information. It is true that some radiographs were slightly rotated, which could introduce error, but the rotations are minor and as such would not affect the measurements based on the vertebral endplates, which represent the majority of data collected. Significant rotational discrepancies could alter the position of the superior posterior corner of C-7 and thus impact sagittal vertical axis. As the rotations were trivial, this potential error is probably only 1 or 2 mm, if it exists at all. The only way to eliminate minor rotation would be to obtain repeated radiographs, thereby exposing the patient to unnecessary radiation, which is unreasonable and unethical.

We have a serious disagreement with the statement that some radiographs were obtained in extension and submit that the improved lordosis has led Drs. Mattei and Teles to this false conclusion. Significant changes in the sagittal alignment of the craniovertebral junction outstrip motion at all subaxial levels unless the craniovertebral junction is fused or there is tremendous instability in one or more of the lower motion segments. The occiput–C1 and C1–2 segments are the most sensitive to flexion and extension and will move greatly before any changes in the subaxial levels are noted. No meaningful change in these segments is present in the radiographs included in the publication or in the others utilized in the study.

This patient group had relatively mild disease without significant deformity, and thus the favorable preoperative lordosis is not unexpected. Prior to this work, it was not known how the lordotic grafts impacted sagittal parameters. We suspect the failure to see each segment increase by 6° is most likely related to surgical technique. The superior vertebral surface naturally inclines from anterior to posterior. Although a serious effort was made to have the endplates parallel prior to graft insertion, if some of the rise of the superior endplate of the caudal body remained after interspace preparation, it would detract from the lordosis the graft provides.

We agree that some improvement in overall lordosis could be due to decreased pain and muscle spasm, as was clearly stated in the *Discussion* section of the paper. Another possibility that we are currently exploring is that the vertebral bodies settled more completely on the grafts, which would account for enhancement of focal segmental lordosis. First, the segment height decreased, which would support this theory. Second, all screws used were variable-

angle screws, which means that the plates could function as rotational dynamic fixators, and, as such, they could allow for the changes noted with time.¹ We are currently investigating this hypothesis.

We hope this discussion has been helpful and again appreciate the interest in cervical alignment following fusion. We look forward to seeing the work of Drs. Mattei and Teles as well as others on this topic in the future.

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Lordoplasty: contribution of many factors in vertebral cement augmentation procedures

TO THE EDITOR: We note with interest the article by Hoppe et al.³ (Hoppe S, Budmiger M, Bissig P, et al: Lordoplasty: midterm outcome of an alternative augmentation technique for vertebral fractures. *J Neurosurg Spine* 24:922–927, June 2016). This is an eloquent description of vertebral height restoration using indirect fracture reduction. The authors describe a method in which the fracture is indirectly reduced by applying a lordotic moment via vertebroplasty cannulas in the affected and adjacent vertebrae, using the facets as a hypomochlion/fulcrum, with subsequent cementation. Balloon kyphoplasty was not used in any case.

We contend that these fractures, particularly recent thoracolumbar and lumbar fractures, are amenable to height restoration from patient positioning, which would have contributed to the technique in this case. While it is not mentioned, we assume that the patients were placed prone with supports under the thorax and iliac crests. By posteriorly inserting instruments to the spine, the operator exerts a downward force to the spine, thus inadvertently “using the facets as a hypomochlion/fulcrum.” As an additional measure for fracture height restoration, hyperextension of the hips provides distraction of the fracture site by traction on the anterior longitudinal ligament, which contributes more to fracture height restoration than balloon kyphoplasty.^{1,4} However, as recognized in the literature internationally, the biggest influence of balloon kyphoplasty is a decrease in the cement leakage rate, which was 10% with vertebroplasty in the series by Hoppe et al., in keeping with quoted rates in the literature.²

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Disclosures

The authors report no conflict of interest.

Response

We thank the authors for their interest in our article. We agree that many factors can contribute to vertebral height restoration in the treatment of mobile vertebral compression fractures. The described technique of lordoplasty can obviously be combined with different pre- and intraoperative positioning and reduction maneuvers as well as with additional balloon kyphoplasty, if adequate restoration of vertebral body height cannot be achieved with this technique alone. Indeed, we often combine lordoplasty and kyphoplasty, but for the sake of a homogeneous study population, we did not include these patients in our study. The rationale for using an additional balloon is not to reduce cement leakage rates but to reduce the fractured endplates with the intention of minimizing posttraumatic disc degeneration.⁵

At only 10%, the leakage rate in our study was rather low, keeping in mind that this finding was based on the evaluation of plain radiographs alone and not on CT. As theoretically described by Bohner et al.,² the main factors influencing the leakage rate are bone permeability and porosity, the diameter of the extravasation path, cement viscosity, intravertebral injection pressure, and the size of the injection cavity. While the bone-specific parameters are immutable, others like cement viscosity and intravertebral injection pressure can be influenced by adapting the cement application process⁴ or by reducing the intraosseous resistance. This can be achieved with the use of an expensive balloon or with a cheaper vertebral body lavage.³ Nevertheless, it is not clear if increasing the size of the injection cavity with kyphoplasty reduces the risk of intravenous leakage significantly. In a prospective study, Berlemann et al.¹ noted that attempting to fill the whole vertebra, rather than just the cavity produced with the kyphoplasty, resulted in leakage rates (33%) similar to those observed during vertebroplasty.

We found lordoplasty to be a safe and cost-effective alternative in the restoration of kyphotic deformity in osteoporotic compression and insufficiency fractures.

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